

## ENZYMATIC THERAPY "CDRPOPA"ED

What Better feels like."

NF Formulas . PhytoPharmica

INTEGRATIVE THERAPEUTICS INC. Tyler Encapsulations > Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 - F: 503.582.0467

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825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 - F: 888.570.6460 (Enzymatic) P: 920.469.9099 ... F: 920.469.4418 (Phyto)

January 17, 2006

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Body Cleanse* Fiber Formula	Gently cleanses and refortifies the digestive tract.*	Proprietary Fiber Blend – psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), marshmallow (althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:		KINCUL
	Dohart C	Dogter

Title: Senior Vice President of Scientific Affairs

1-17-06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Chief Operations Officer

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Body	Helps maintain healthy	Proprietary Fiber Blend – psyllium (Plantago
Cleanse* Fiber Formula	gastrointestinal function and improves colon health.*	ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin
Tormula	improves colon nearth.	(from citrus fruit), marshmallow (althaea
		officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-11-06

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Sincerely.

Michael P. Devereux Chief Operations Officer